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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,997	12/18/2001	Judy Ruckman	NEX82/D	8763

25871 7590 09/09/2003

SWANSON & BRATSCHUN L.L.C.  
1745 SHEA CENTER DRIVE  
SUITE 330  
HIGHLANDS RANCH, CO 80129

EXAMINER

ZITOMER, STEPHANIE W

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/024,997	RUCKMAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Stephanie Zitomer	1634	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 April 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3-5 is/are allowed.
- 6) ☒ Claim(s) 1,2,6 and 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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### DETAILED FINAL ACTION

#### Application status

1. Receipt of the amendment filed April 14, 2003 is acknowledged.
2. The amendments to the specification and claims have been entered and reviewed by the examiner. Applicant's remarks have been fully considered. The amendment to the claims has been found to introduce new matter.

#### Rejection under 35 U.S.C. 112, first paragraph: New matter and lack of written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 2, 6 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims in question are drawn to methods of treating disease by administration of a nucleic acid ligand to a  $\beta_3$  integrin wherein the disease is "one resulting from platelet activation", a "deep vein thrombosis" and one "in which [ $\beta_3$ ] activation is a contributing factor", respectively, Claims 1, 2 and 6 have been amended by addition at the end of each claim of "to an individual in need thereof". The amended phrase is not supported by the specification. It is not defined in the definitions at pages 13-15 or elsewhere. The specification describes potential therapeutic applications of nucleic acid ligands which **inhibit** interaction between platelet-expressed integrins and their cognate ligands to prevent clot formation in patients susceptible to deep vein thrombosis and to treat patients with acute coronary syndromes (page 21). Other diseases potentially treatable with nucleic acid ligands to a  $\beta_3$  integrin are listed at page 22. However, the specification does not

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describe what particular conditions, or symptoms, constitute an individual's "need" of treatment with a nucleic acid to a  $\beta_3$  integrin. In this regard, the specification further fails to describe "administering" to "an individual in need" a nucleic acid ligand to a  $\beta_3$  integrin, e.g., dosage forms, dosages, routes of administration. Absent such critical information one of skill in the art would not have recognized that applicant was in possession of the claimed invention of "administering a [nucleic acid ligand to a  $\beta_3$  integrin]...to an individual in need thereof" at the time the application was filed. In addition to enablement the first paragraph of 112 requires a "written description". As set forth by the Court in *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date applicant was in possession of the claimed invention.

*The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.*

**Rejections under 35 U.S.C. 112, second paragraph; Indefiniteness**

4. Claims 1, 2, 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) In claim 1, the amended phrase, "to an individual in need thereof" is determinate with regard to "in need" because such "need" is not defined in the claims or in the specification. Furthermore, the phrase lacks antecedent basis because it lacks a recited or implicit relationship with "disease" and "platelet activation". It is suggested to clarify "to an individual in need thereof" and its relationship with "disease" and "platelet activation".

(b) In claim 2, the amended phrase, "to an individual in need thereof" is determinate with regard to "in need" because such "need" is not defined in the claims or in the specification. Furthermore, the phrase lacks antecedent basis because it lacks a recited or implicit relationship

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with "deep vein thrombosis". It is suggested to clarify "to an individual in need thereof" and its relationship with "deep vein thrombosis".

(c) In claims 6-7, the amended phrase, "to an individual in need thereof" is determinate with regard to "in need" because such "need" is not defined in the claims or in the specification. Furthermore, the phrase lacks antecedent basis because it lacks a recited or implicit relationship with "disease" and the integrin "activation". It is suggested to clarify "to an individual in need thereof" and its relationship with "disease" and the integrin "activation".

#### **Conclusion**

5. **Claims 1, 2, 6 and 7 are rejected. Claims 3-5 were previously allowed.**
6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 10:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is

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(703) 308-4242. The unofficial fax number is (703) 308-8724. The examiner's Rightfax number is 703-746-3148.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196. For questions and requests relating to formal matters contact LIE Chantae Dessau at 703-605-1237.



Stephanie Zitomer, Ph.D.

September 5, 2003

**STEPHANIE W. ZITOMER**  
**PRIMARY EXAMINER**